

CLAIMS

We claim:

Sub B₁ 1. A rapidly dispersing solid therapeutic dosage form comprised of a water insoluble compound existing as a nanometer or micrometer particulate solid which is surface stabilized with one or more surface modifiers of which at least one may be a phospholipid, the particulate solid dispersed throughout a bulking matrix optionally also including a releasing agent forming a therapeutic dosage form when dried which when the dosage form is introduced into an aqueous environment the bulking/releasing matrix is substantially completely disintegrated within less than 2 minutes thereby releasing the water insoluble particulate solid in an unaggregated and/or unagglomerated state.

2. The rapidly dispersing solid dosage form of claim 1 wherein the water insoluble particulate solid component consisting essentially of a composition of a water insoluble substance comprising particles of a therapeutically useful water insoluble or poorly water soluble compound, a phospholipid and optionally also at least one non-ionic, anionic, cationic or amphipathic surfactant, wherein a volume weighted mean particle size of the water insoluble particle is 5 micrometers or less.

Sub B₂ 3. The rapidly dispersing solid dosage form of claim 1 wherein the bulking/releasing matrix component is selected from saccharides, polysaccharides, humectants, natural or synthetic polymers inorganic additives, or cellulose based polymers.

B 4. The rapidly dispersing solid dosage form of claim 3 wherein the poly¹of saccharide or polysaccharide is mannitol, trehalose, lactose, sucrose, sorbitol, dextrose, mulodextrose or maltose.

5. The rapidly dispersing solid dosage form of claim 3 wherein the humectant is glycerol, propylene glycol or polyethylene glycol.

6. The rapidly dispersing solid dosage form of claim 3 wherein the natural or synthetic polymer is gelatin, dextran, starches, polyvinylpyrrolidone, a poloxamer or an acrylate.

7. The rapidly dispersing solid dosage form of claim 3 wherein the inorganic additive

is colloidal silica or tribasic calcium phosphate.

8. The rapidly dispersing solid dosage form of claim 3 wherein the cellulose based polymer is microcrystalline cellulose, hydroxymethyl cellulose, hydroxypropyl cellulose or methylcellulose.

add B3 9. The rapidly dispersing solid dosage form of claim 1 wherein the disintegration time in an aqueous medium is less than 2 minutes and preferably less than 60 seconds, more preferably less than 30 seconds, and the most preferably less than 10 seconds.

10. The rapidly dispersing solid dosage form of claim 1 further containing an effervescent agent, a binding agent, a flavor, a polymeric coating on the external surface of the dosage form, a color or combinations thereof.

add B4

add
20

add
20

add
75